PTO/SB/21 (08-00) Rease type a plus sign (+) inside this box --> + Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Onder the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. **Application Number** 09/546,573 TRANSMITTAL Filing Date April 10, 2000 **FORM** Holten-Andersen, Mads, et. al. First Named Inventor (to be used for all correspondence after initial filing) Group Art Unit 1642 **Examiner Name** Rawlings, S. Total Number of Pages in This Submission Attorney Docket Number 19829000310 ENCLOSURES (check all that apply) After Allowance Communication to Assignment Papers Fee Transmittal Form (for an Application) Group Appeal Communication to Board of Fee Attached Drawing(s) Appeals and Interferences Appeal Communication to Group Amendment / Response Licensing-related Papers (Appeal Notice, Brief, Reply Brief) Petition Routing Slip (PTO/SB/69) After Final Proprietary Information and Accompanying Petition Petition to Convert to a Affidavits/declaration(s) Status Letter **Provisional Application** Power of Attorney, Revocation Other Enclosure(s) Extension of Time Request Change of Correspondence Address (please identify below): Return Mailroom Postcard: Applicant Terminal Disclaimer requests a One Month Extension of Express Abandonment Request Request for Refund Time: Authorization to Charge Deposit Account No. 20-1430 in the amount of Information Disclosure Statement CD, Number of CD(s) The Commissioner is authorized to charge any additional fees to Certified Copy of Priority Deposit Account 20-1430. Remarks Document(s) Response to Missing Parts/

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm	Townsend and Townsend and Crew LLP		
and Individual name	Kevin Bastian	Reg No. 34,774	
Signature	8		
Date	June 5, 2001		

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SF 1232582 v1

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Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53



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TOWNSEND and TOWNSEND and CREW LLP

By: JUR R. Mull

AH R. Clarke



<u>PATENT</u>

Attorney Docket No.: 019829000310 Client Reference No.: 96-185-4

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HOLTEN-ANDERSEN, MADS

Application No.: 09/546,573

Filed: April 10, 2000

For: TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES TYPE-1 (TIMP-1) AS A CANCER MARKER Examiner:

Rawlings, S.

Art Unit:

1642

RESPONSE TO RESTRICTION

REQUIREMENT

RECEIVED

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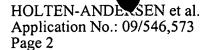
TECH CENTER 1600/2900

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

The following is offered in response to the Office Action mailed April 5, 2001. Applicants elect with traverse to prosecute the claims of Group I (claims 1-5, 13-19, 27, and 37) drawn to methods of determining whether a person is likely to have cancer by determining TIMP-1 levels in a sample. Applicants particularly traverse the restriction between Group I and Group III (claims 1-5, 13, 14, and 28-37), drawn to methods of detecting early stage cancer by determining TIMP-1 levels in a sample.

According to the MPEP, where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. See, the MPEP at 803.01. In establishing that an "undue burden" would exist for co-examination of claims, the Examiner must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the Examiner must show that the restricted groups have a separate classification, acquired a



separate status in the art, or that searching would require different fields of search (MPEP at § 808.02).

In the present restriction, all the groups are indicated as classified under Class 435 subclass 7.23 or class 204, subclass 450. The Examiner has provided little or no reasoning to show that the groups meet the other two criteria required under §808.02. Instead, the Examiner simply states that, as between Groups I and III, the objectives are different. The Examiner does not explain why the different objectives (detection of the likelihood of cancer vs. the detection of early stage cancer) would lead to different searches.

In addition, applicants note that claims 1-5, 13, 14, and 37 have been placed in both Groups I and III. The courts have long held that an Examiner may <u>not</u> reject a particular claim on the basis that it represents "independent and distinct" inventions. *See, In Re Weber, Soder and Boksay* 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

The courts have definitively ruled that the section of the patent statute authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. See, In Re Weber, Soder and Boksay, In Re Haas I and In Re Haas II. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in In Re Weber, Soder and Boksay:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

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In light of the above, Applicants respectfully request that the restriction be withdrawn. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (415) 576-0200.

Respectfully submitted,

Reg No. 34,774

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KLB